UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against-

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC

Defendants and Counterclaimants.

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17 Civ. 9922

OPINION and ORDER

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Following the Federal Drug Administration's ("FDA's") approval of Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc.'s ("Ferring" or "Plaintiffs") NOCDURNA product, Defendants Serenity Pharmaceuticals, LLC ("Serenity"), Reprise Biopharmaceutics LLC ("Reprise"), Avadel Specialty Pharmaceuticals LLC ("Avadel") (together, "Defendants,") have moved for a preliminary injunction to block the commercial release and administration of the drug.

Before this Court is a significant skirmish in the 16-year-old battle between the parties over development of therapies to treat nocturia due to nocturnal polyuria, a disease of the kidneys which causes excessive nighttime urination. The contours of this conflict can found in this Court's past opinions.[1]

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[1] See e.g., Ferring v. Allergan, 253 F.Supp.3d 708 (S.D.N.Y. 2015) ("Equitable Estoppel Opinion") and Ferring v. Allergan, 316 F.Supp.3d 623 (S.D.N.Y. 2018) ("Standing Opinion").

Based on the conclusions set forth below, the motion for preliminary injunction is denied.

I. Prior Proceedings

Familiarity with the facts of this case and the related 2012 case, Ferring B.V. v. Allergan, Inc., No. 12 Civ. 2650 (RWS) (the "2012 Action"), is assumed. The following summary is provided only as necessary to resolve the pending motion.

On April 28, 2017, Ferring commenced this action in the District of Delaware against Allergan, Inc. ("Allergan"), Serenity, and Reprise, seeking a declaratory judgment of patent invalidity, unenforceability, and non-infringement with respect to Defendants' United States Patent No. 7,405,203 (the "203 Patent"), United States Patent No. 7,579,321 (the "321 Patent"), and United States Patent No. 7,799,761 ("the 761 Patent") (together, the "Patents in Suit"). See generally Pl. Compl., ECF No. 1.

Ferring amended its Complaint on June 30, 2017. ECF No. 18.

After briefing from parties on the issue of jurisdiction in Delaware and transferability, the case was transferred to this District, where it was designated related to the 2012 Action. See ECF Nos. 25-27, 58. Around the same time, Allergan was voluntarily dismissed from the case. See ECF No. 35.

Following contention over whether Ferring's NOCDURNA drug would be approved, and with Serenity's motion to dismiss for lack of jurisdiction pending, Ferring received FDA approval of its New Drug Application ("NDA") on June 21, 2018. See ECF No. 99.

On June 28, 2018 Serenity and Reprise, together with newly-joined patent licensee Avadel, answered Ferring's Amended Complaint and asserted various counterclaims, including patent infringement and willful patent infringement by NOCDURNA of the 203 Patent and the 321 Patent. ECF No. 101.

On July 19, 2018, Ferring moved to strike certain of Serenity's defenses and to dismiss certain of its counterclaims,

including those alleging patent infringement under 35 U.S.C. § 271(a). ECF No. 114 at 13-14.

On July 23, 2018, Serenity moved for a preliminary injunction to block the commercial release of NOCDURNA. ECF No. 117.

On July 27, 2018, parties entered into a stipulated Case Management Plan, scheduling the Markman claim construction hearing for October 15, 2018,[2] and an accelerated trial on the merits for January 14, 2019. ECF No. 131.

On August 2, 2018, Serenity filed a cross-motion to strike certain of Ferring's affirmative defenses asserted in its July 19 motion to strike and dismiss. ECF No. 136.

On August 14, 2018, Serenity filed a motion for judgment on the pleadings. ECF No. 148.

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[2] The Markman has since been adjourned to November 13, 2018 at 10:00AM.

On August 20, 2018, Ferring withdrew its July 19, 2018 motion to strike and dismiss certain of Serenity's affirmative defenses. ECF No. 160.

On September 10, 2018, Ferring moved for summary judgment on the issue of invalidity under 35 U.S.C. § 112 for lack of enablement, ECF No. 178, and for non-infringement or, alternatively, invalidity due to lack of written description, ECF No. 182.

On September 21, 2018, Serenity moved for judgment on the pleadings on the issue of collateral estoppel. ECF No. 206.

On October 16, 2018, a six-day hearing commenced on Serenity's motion for a preliminary injunction to block the commercial release and administration of NOCDURNA. ECF No. 117. Seven witnesses were called and examined, including economic and pharmacological experts. Dozens of exhibits and demonstratives were introduced by each side. On October 26, 2018, the hearing concluded, at which point the motion for preliminary injunction was marked fully submitted.

II. The Facts

At the preliminary injunction hearing, factual issues were raised involving patent infringement, invalidity, unenforceability, and damages, among others going to the merits of this dispute. Final determinations on these issues and others will be made in due course: claim construction will be conducted after the scheduled Markman hearing and issues of infringement will be determined after trial. It is for that reason, and the reasons that follow, that Serenity's preliminary injunction motion is denied.

Because of the interrelatedness of these factual issues, detailed findings of fact will be deferred and made following the scheduled Markman hearing and trial.

The Defendants' NOCTIVA has been on the market since May 1, 2018. Ferring unless enjoined will launch NOCDURNA on November 8, 2018. The Defendants have presented evidence as to its "first mover advantage" and the damages resulting from Ferring's anticipated contracts with Pharmacy Benefit Managers.

III. The Patents in Suit

On May 7, 2002, Ferring filed a Great Britain Patent Application No. GB0210397.6 (the "GB Application"), for a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption," with no inventor named. In the following months and years, Dr. Fein and Ferring filed several patents involving this subject matter. See Ferring B.V. v. Allergan, Inc., No. 12 Civ. 2650 (RWS), 2015 WL 5671799, at *2-*3 (S.D.N.Y. Sept. 22, 2015) (detailing the many Fein and Ferring patents).

On September 20, 2002, Ferring filed Patent Cooperation Treaty ("PCT") Application IB02/04036, claiming the same subject matter as the GB Application and naming Dr. Fein as one of its inventors. Ferring v. Allergan, 253 F. Supp. 3d 708, 711 (S.D.N.Y. 2015).

On May 7, 2003, Ferring filed a modified PCT Application IB03/02368 (the "PCT Application") that claimed priority to the GB Application, but did not include low dose and sublingual claims. Ferring, 166 F. Supp. 3d at 418. Nor did it name Dr. Fein as an inventor. Id.

On November 12, 2003, Dr. Fein, through counsel, filed continuation-in-part United States patent application 10/706,100 based off his PCT application US2003/014463. Ferring v. Allergan, 253 F.Supp.3d 708, 713 (S.D.N.Y. 2015). U.S. patent application 10/706,100 issued as U.S. Patent Application 2004/0138098 A1 on July 15, 2004. Id.

On May 4, 2007, Dr. Fein, through counsel, filed U.S. patent application 11/744,615 as a division of his previously filed U.S. patent application 10/706,100. Id.

On July 15, 2008, Dr. Fein, through counsel, filed U.S. patent application 12/173,074 as a continuation of his previously filed U.S. patent application 11/744,615. Id.

On July 29, 2008, Dr. Fein's U.S. patent application 11/744,615 issued as the 203 Patent. Id. The 203 Patent is "directed to a pharmaceutical composition" of desmopressin "effective to establish a steady plamsa/serum desmopressin concentration in the range of from about .1 pg/mL plasma/ serum to about 10.0 pg/mL plasma/serum." ECF No. 185-3. The 203 Patent includes the following claims:

(1) A method of treating nocturia, primary nocturnal enuresis, or incontinence, or for inducing voiding postponement, said method comprising administering to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration of no greater than 10 pg/ml, which is to be maintained for about four to six hours.

(6) A method of claim 1, comprising administering said composition by transmucosal delivery.

(10) A method of inducing an antidiuretic effect in a patient comprising the step of administering to a patient a pharmaceutical composition comprising desmopressin by transmucosal, transdermal, or intradermal delivery in an amount and for a time sufficient to establish a maximum serum/ plasma desmopressin concentration no greater than 10 pg/ml.

Id. at 27.

On June 18, 2009, Ferring filed U.S. patent application 12/487,116 as a continuation of its previously filed U.S. patent application 10/513,437. Id. at 712.

On August 25, 2009, Dr. Fein's patent application 12/173,074 issued as U.S. Patent No. 7,579,321 ("321 patent"). Id. The 321 patent is "directed to a pharmaceutical composition comprising .5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier." ECF No. 185-8 at 3. Its common

specification is identical to the 203 Patent's. Id. The 321 Patent includes the following claims, as relevant:

> (1) A method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising delivering to the bloodstream of the patient an amount of desmopressin no more than about 2 ng/kg by intranasal, transdermal, intradermal, transmucosal, or conjunctival administration, said amount being therapeutically effective to produce an antidiuretic effect lasting for no more than between about 4 and hours.
>
> (12) The method of claim 1 or 8 comprising administering the desmopressin by transmucosal administration.

Id. at 29.

On October 12, 2010, Adriana Burgy of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., counsel of record for Ferring, filed a request for reexamination of Dr. Fein's 203 Patent before the United States Patent and Trademark Office ("PTO"). Id.

On January 19, 2011, the PTO denied Ferring's request for reexamination. Id.

On May 24, 2011, Ferring's U.S. patent application 12/487,116 issued as U.S. Patent No. 7,947,654 ("the 654 Patent"). Lloyd Decl. Ex. 10 at 2. Id.

Among the issues presented with regard to patent infringement are: whether NOCDURNA as administered will embody either or both the "maximum desmopressin plasma/ serum concentration of no greater than 10 pg/ml" limitation from Claim 1 of the 203 Patent and the "transmucosal delivery" limitations from Claim 6 of the 203 Patent and Claim 12 of the 321 Patent. Central to these issues is the threshold construction question of whether Dr. Fein's patent are constrained to a calculable upper dose limit corresponding to a maximum plasma concentration.

IV. The Applicable Standard

Preliminary injunctions are "drastic remed[ies] that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." Mazurek v. Armstrong, 520 U.S. 968, 972 (1997). A party seeking a preliminary injunction must establish:

> [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest.

Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008).

The general purpose of a preliminary injunction is to avoid irreparable injury to the movant and to preserve the court's power to render a meaningful decision after a trial on the merits. See WarnerVision Entm't Inc. v. Empire of Carolina, Inc., 101 F.3d 259, 261 (2d Cir. 1996). A preliminary injunction is an "extraordinary remedy" that is never awarded "as of right." Winter, 555 U.S. at 24; see also Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 65 (2d Cir. 2007). Whether injunctive relief should issue or not "rests in the sound discretion of the district court which, absent abuse of discretion, will not be disturbed on appeal." Reuters Ltd. v. United Press Int'l, Inc., 903 F.2d 904, 907 (2d Cir. 1990) (citation omitted).

A party seeking a preliminary injunction must establish: (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; (2) irreparable harm; and (3) that issuance of the injunction

would be in the public interest. See Oneida Nation of N.Y. v. Cuomo, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotations and citations omitted); Red Earth LLC v. United States, 657 F.3d 138, 143 (2d Cir. 2011). Where, as here, "the relevant facts either are not in dispute . . . or when the disputed facts are amenable to complete resolution on a paper record," a hearing is not required to resolve a motion for preliminary injunction. Charette v. Town of Oyster Bay, 159 F.3d 749, 755 (2d Cir. 1998) (citations omitted).

Pursuant to Federal Rule of Civil Procedure 52(a), in granting or refusing a preliminary injunction, the court shall set forth "the findings of fact and conclusions of law" which constitute the grounds of its action. The Second Circuit has stated that "[t]hese findings are not conclusive, and may be altered after a trial on the merits." Visual Scis., Inc. v. Integrated Commc'ns Inc., 660 F.2d 56, 58 (2d Cir. 1981) (citing Hamilton Watch Co. v. Benrus Watch Co., 206 F.2d 738, 740 (2d Cir. 1953)).

V. Defendants' Motion for a Preliminary Injunction is Denied

Movants submit that a preliminary injunction is necessary to avoid the "severe and irreparable harm" that would result if NOCDURNA is administered before the conclusion of a trial on the merits. Defs.' Memo. at 7, ECF No. 118. Their position is that NOCDURNA infringes several claims of Dr. Fein's 203 and 321 Patents. Id. at 7-8.

Ferring contends that Movants have not established irreparable harm and, in any event, NOCDURNA does not infringe the asserted claims of the 203 and 321 Patents because its "doses are greater than the doses required by the claims *as* properly construed" and because Movants "have failed to prove that NOCDURNA is absorbed 'transmucosally.'" Pl. Brief in Opp. ("Pl. Opp.") at 9, ECF No. 193.

i. Likelihood of Success on the Merits

To establish a likelihood of success on the merits Serenity must demonstrate both that administration of NOCDURNA likely infringes at least one of the claims in Dr. Fein's 203 or 321 Patents *and* that the Patents are likely to withstand

Ferring's invalidity challenge. See Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 141 F.3d 1084, 1088 (Fed. Cir. 1998). If a "substantial question concerning either infringement or validity" exists then a preliminary injunction will not issue. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350-51 (Fed. Cir. 2001); see also AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010).

a. Infringement of the Dose Limitation, If Any

A central question that remains unanswered is whether, and to what degree, the 203 and 321 Patents are confined to a calculable dose range corresponding to the plasma concentration listed in Claim 1 of the 203 Patent. Claim 1 is directed to:

> "A method of treating nocturia, primary nocturnal enuresis, or incontinence, or for inducing voiding postponement, said method comprising administering to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration of no greater than 10 pg/ml," which is to be maintained for "about four to six hours."

ECF No. 185-3 at 27.

Movants contend that NOCDURNA, which is administered in doses of "27.7 mcg once daily" for women and "55.3 mcg once

daily" for men for the treatment of nocturia due to nocturnal polyuria, satisfies the "dose of desmopressin sufficient to achieve a maximum desmopressin plasma/serum concentration no greater than 10 pg/ml" from Claim 1. Defs.' Ex. A at 2. Movants rely on the linear relationship between doses of desmopressin and plasma/serum concentrations to support an inference of infringement. Id. at 3-4. Infringement of Claim 1 is established, they claim, by the mathematical relationship between doses of NOCDURNA and the resulting physiological response (plasma concentration expressed as Area Under the Curve ("AUC") or Maximum Serum Concentration ("Cmax")). Id. at 7 ("Ferring's NDA Products contain a dose of desmopressin sufficient to maintain a maximum concentration of about .5-10 pg/ml for about four to six hours.").

Ferring counters by reference to intrinsic evidence supporting a "dose limitation" based on Dr. Fein's inclusion in the Patents' shared common specification of the dose range ".5ng to 20 µg desmopressin." ECF No. 185-3 at 3; 321 Patent, ECF No. 185-8 at 2. Ferring avers that, "under a proper claim construction," this dose range limitation constrains the Patents to doses between .5 ng to 20 µg. Pl. Opp. at 13. Were the Court to adopt Ferring's construction based on the language of the

common specification, NOCDURNA's dose range would not infringe the asserted claims' dose ranges. Id. at 13. ("The two approved formulations for NOCDURNA contain either 25 µg or 50 µg of desmopressin. These doses are greater than the 20 µg upper dose limit of the asserted claims, and thus Ferring cannot infringe[.]").

But the common specification of the Patents in Suit is not the only place a specific low dose range of desmopressin is contemplated. Dr. Fein's edits to the GB priority application also suggest an intent to limit the dosage of his inventions to a particular range. Pl. Opp. at 7. After Dr. Fein's edits, the GB application read, "comparatively lower doses are specifically contemplated, for example from .5ng to 20,000ng (20 µg)[.]" Id. (internal parentheses omitted). Dr. Fein's reference to the specific .5 ng to 20 µg range presents a "substantial question" with respect to whether NOCDURNA, as administered in doses of 27 and 55 µg, infringes on the Patents in Suit and the plasma concentrations therein. See Amazon, 239 F.3d at 1350-51.

At the same time, Movants have presented plausible evidence suggesting doses of NOCDURNA as administered infringe upon the 203 Patent's claimed plasma concentrations *even if* the

Patents in Suit are limited to a particular dose range. Mayersohn Decl. ¶ 78, ECF No. 233 (noting both that a POSITA "can calculate the oral dosage of desmopressin needed to achieve the plasma/ serum concentration within the claimed range" and that "use of Ferring's NOCDURNA product will infringe the asserted claims containing these limitations *under either [party's] construction*.") (emphasis added); Id. ¶ 89 (The Patent Examiner recognized the pharmacokinetic linearity at play and the ease with which a POSITA could practice the invention: "[a]chieving the [plasma concentration] would amount to nothing more than routine optimization.")

The linear relationship between plasma concentration and dosage plausibly suggests infringement by NOCDURNA of the Patents in Suit. But the burden on a preliminary injunction is higher than that. See Benitez v. King, 298 F.Supp.3d 530, 536 (W.D.N.Y. 2018) ("The standard for demonstrating a likelihood of success on the merits . . . is far more demanding than the plausibility standard[.]"). Ferring's contention that the 203 Patent is—because it has to be—limited to the .5 ng to 20 µg range from the common specification is likewise plausible.

The parties dispute plausibly and in good faith the meaning of asserted claims which are the subject of an imminent Markman claim construction hearing. Parties' have repurposed claim construction arguments at the preliminary injunction hearing and in their briefs. See Defs.' Memo. at 3-4 ("[A]s Movants previously detailed in their claim construction briefs, Ferring's efforts to rewrite the actual language of the asserted patents do violence to the central tenets of claim construction"); Pl. Opp. at 7-8 ("[T]he asserted claims *should be construed as* limited to 'low doses' of desmopressin"). The significance of the upcoming claim construction is demonstrated by Serenity's submission of its 106-page claim chart.

A full patent infringement analysis will be conducted following the hearing and trial. See Catorek v. Kobayashi Ventures, LLC, No. 08-cv-5706 (NRB), 2009 WL 2850760, at *7 (S.D.N.Y. Aug. 31, 2009) (Dismissing two "substantive patent motions [which] require the Court to construe the claims in the various patents at issue" because "claim construction is premature" before a Markman hearing.).

b. Infringement of the Transmucosal Limitation

Several claims in both the 203 and 321 Patents require desmopressin be delivered to the bloodstream by "transmucosal delivery."[3] Claim 6 of the 203 Patent, for example, is a "method of Claim 1, comprising administering said composition by transmucosal delivery." Id. Parties agree that "transmucosal delivery" involves absorption of a drug across a mucosal membrane, such as the oral mucosa under the tongue. Pl. Opp. at 17; see also 321 Patent, ECF No. 185-8 (describing desmopressin's "absor[ption] across the sublingual mucosa for systemic distribution"). The disagreement, then, is about whether NOCDURNA as administered is necessarily absorbed in the oral mucosa and therefore infringes upon the "transmucosal delivery" limitation. Pl. Opp. at 17 ("[T]he documents cited by Movants failed to show that the desmopressin in Ferring's NOCDURNA drug product will enter the bloodstream via transmucosal absorption") (cleaned up); Defs.' Claim Chart at 19

[3] ECF No. 185-5, ECF No. 185-8; see also Pl. Opp. at 8-9 (noting that "[c]laims 2, 6, 10, 11, 12, 13, 14, and 15 of the 203 Patent each have a requirement that desmopressin be delivered by 'transmucosal delivery'" and that "[c]laims 1, 2, 3, 5, 6, 7, 12, and 19 of the 321 Patent each have a requirement that desmopressin be delivered by 'transmucosal administration.'").

(Arguing that, because "at least a portion of the desmopressin in [NOCDURNA] is administered by transmucosal delivery," there must be literal infringement of Claims 6 and 10 of the 203 Patent, among others).

Ferring's formulation expert, Dr. Jennifer Dressman, submits that Movants have "failed to show that the desmopressin in Ferring's NOCDURNA drug will enter the bloodstream via transmucosal absorption," and thus have failed to establish infringement on the transmucosal route of administration. Dressman Decl. ¶¶ 65, 76-77 ("[S]imply because NOCDURNA is an orodispersible tablet does not mean that the desmopressin the formulation is absorbed through the oral mucosa."). Dressman "disagrees completely" with Movants' attempt to link the site of administration (where the pill is placed) with its site of absorption (where the desmopressin is absorbed into the blood). Id. ¶ 72. According to Dr. Dressman, "rapid disintegration of NOCDURNA in the oral cavity does not mean that desmopressin is absorbed in the oral cavity." Id. ¶ 67. In addition, Dr. Dressman points out the "unsuitab[ility]" of desmopressin for absorption in the oral cavity and the possibility that the "site(s) of absorption can be quite different to the site where the drug is administered." Id. ¶ 50.

Movants characterize Ferring's position that the transmucosal route of administration is not infringed by NOCDURNA as "preposterous." Defs.' Reply Br. at 4. In response, Movants point to representations that Ferring made to the FDA and papers it published on the administration and absorption of desmopressin. Id. (noting, among other things, Ferring's statement that "desmopressin is immediately available for absorption via the membranes of the mouth").

Still, Ferring has presented a "substantial question" as to whether NOCDURNA is necessarily absorbed at its site of administration. See Amazon, 239 F.3d at 1350-51. Without the benefit of a Markman hearing and a trial to determine on its own whether NOCDURNA, in its current recommended administration, likely infringes the "transmucosal absorption" limitation, a likelihood of infringement has not been shown.

Accordingly, Ferring's contention that the claims of the 203 and 321 Patents are limited to a particular dose range presents, at a minimum, a "substantial question" with respect to the claims at issue. Amazon, 239 F.3d at 1350-51. Movants have not adequately addressed this suggested "dose limitation," nor

have they presented a clear dose limitation of their own. Pl. Opp. at 13. Ferring has likewise raised a substantial question regarding Movants' claim that NOCDURNA is necessarily absorbed transmucosally. Id. ("If [non-movant] raises a substantial question concerning [infringement] . . . that [movant] cannot prove lacks substantial merit, the preliminary injunction should not issue.") (cleaned up). Because likelihood of success is a necessary prerequisite to the issuance of a preliminary injunction, without it the motion must be denied.[4] See Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446, 1457 (Fed. Cir. 1988), see also United States v. Weikert, 504 F.3d 1, 5 (1st Cir. 2007) ("[I]f the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity.")

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[4] Because determining patent infringement is a two-step process—"[1] interpret the claims to determine their scope and meaning; [2] compare the properly construed claims to the allegedly infringing device"—a likelihood of infringement analysis is ill-suited for a pre-Markman procedural posture. See generally Parker-Hannifan Corp. v. Wix Filtration Corp., No. 06-cv-98, 2006 WL 3028706, at *3 (N.D. Cal. Oct. 24, 2006) (denying preliminary injunction motion because "without the benefit of a Markman hearing, the court is not in a position to interpret definitively the patent claims and their terms[.]")

ii. Irreparable Harm in the Absence of an Injunction

Defendants' burden to establish irreparable harm is high. See PHG Technologies, LLC v. St. John Companies, Inc., 469 F.3d 1361, 1364; see also Amazon, 239 F.3d at 1350.

Movants have contended that, as the first product approved by the FDA for its indication, NOCTIVA has achieved an exclusive market position that would be irreparably harmed were NOCDURNA to come to market. Pl. Memo. at 10. In support of this position, Movants submit an expert declaration from economist Dr. Christopher Vellturo. See generally Vellturo Decl. Vellturo concludes that NOCTIVA's "significant and long-lasting" first-mover advantage in the market would suffer correspondingly significant and long-lasting harm without an injunction. Id. at ¶¶ 11-12. This harm, according to Vellturo, would last "well beyond the completion of trial," even if NOCDURNA is eventually taken off the market. Id. Vellturo notes that among the benefits of being a first-mover in a "nascent marketplace" is the benefit of "capturing an initial base of loyal patients and prescribing physicians." Id. ¶ 14.

Vellturo also opines that, if NOCDURNA were launched, it would "forever alter the market" and "irreparably affect the [Court's] ability to calculate damages." Id. ¶ 15. According to Vellturo, Movants would suffer loss of revenue in the form of lost market share, profitability reduction, permanent price erosion, and more. Id. ¶¶ 18-20.

However, while NOCTIVA is a first mover as the earliest drug approved for its indication, without establishing patent infringement, Movants have no legal right to market exclusivity. Second, while Vellturo characterizes Movants as "poised" to "captur[e] an initial base of loyal patients and prescribing physicians," NOCTIVA's performance in the market tells a different story. Id. ¶ 14. Prescriptions for NOCTIVA have been filled just 2,452 times at retail outlets during its first 24 weeks on the market. See Pl. Opp. at 20; Carter Decl. ¶¶ 1, 21. Avadel's net sales during this period, estimated to be $289,000, represents less than one percent of Avadel's total net sales—and even less when considering royalties Avadel pays Serenity and Reprise. Id.

While it is certainly possible Movants will suffer lost sales as NOCDURNA enters the market, lost sales alone do

not establish irreparable harm. Automated Merch. Sys., Inc. v. Crane Co., 357 Fed. App'x 297, 300 (Fed. Cir. 2009); see also Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991) ("[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.").

Movants' claim that "there may be permanent price erosion" even if NOCDURNA is withdrawn from the market after trial is speculative. Defs.' Memo at 18 ("[I]t may not be possible for Avadel to restore NOCTIVA to the price levels in place prior to Ferring's at-risk launch"). Movants themselves admit that this possibility "depend[s] on the existence of intervening events." Id.

Movants further speculate that Avadel and Serenity's research and development programs will be irreparably harmed if NOCDURNA comes to market. Id. at 18. As Ferring notes, however, Serenity has already been paid $135 million in up-front fees for NOCTIVA and is unlikely to be materially affected by whatever lost sales are realized in this interim period. Pls. Opp. at 22. And for Avadel, of whose total revenue NOCTIVA comprises less

than one percent, it is not plausible that research and development will be harmed, let alone irreparably. Id. at 20.

Finally, Movants claim that Ferring's "NOCDURNA label and product approval history is likely to taint the safety reputation of NOCTIVA" based on NOCDURNA's warning label, which instructs patients to limit fluid intake, and could be confused with its own. Defs.' Memo. at 19 ("[T]he restrictive labeling on the NOCDURNA product presents a substantial risk that physicians will be reluctant to prescribe *any* desmopressin product[.]"). This contention is speculative and unsupported. See Lowe Decl. ¶ 6; Pl. Opp. at 28.

Movants have not established that NOCDURNA's entrance into the market would cause irreparable harm which cannot be compensated for by money damages. PHG Technologies, LLC v. St. John Companies, Inc., 469 F.3d 1361, 1364 (Fed. Cir. 2006)("[M]ovant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors."). For this reason, and the reasons above, the motion for preliminary injunction is denied. In the event that Defendants establish patent infringement, appropriate relief can be fashioned in due course.

VI. Conclusion

For the reasons set forth above, Defendants' motion for a preliminary injunction is denied with leave to renew.

It is so ordered.

New York, NY
November 5, 2018

ROBERT W. SWEET
U.S.D.J.